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**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

CHIESI USA INC. and)
CHIESI FARMACEUTICI S.P.A.)
)
Plaintiffs,)
)
v.)
)
GLAND PHARMA LTD.,)
)
Defendant.)

C.A. No. _____

Document Filed Electronically

COMPLAINT

Plaintiffs Chiesi USA Inc. and Chiesi Farmaceutici S.p.A. (collectively, “Chiesi” or “Plaintiffs”) by its undersigned attorneys, for its Complaint against Defendant Gland Pharma Ltd. (“Gland” or “Defendant”) herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 9,295,687 (“the ’687 patent” or “the patent in suit”), attached hereto as Exhibit A.

THE PARTIES

2. Chiesi USA Inc. is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 175 Regency Woods Place, Suite 600, Cary, North Carolina 27518. Chiesi USA Inc. is a wholly owned subsidiary of Chiesi Farmaceutici S.p.A.

3. Chiesi USA Inc. is the owner of New Drug Application (NDA) No. 204958, which was approved by the U.S. Food and Drug Administration (FDA) for the manufacture and sale of Kengreal[®] (cangrelor) for injection.

4. Chiesi Farmaceutici S.p.A. is a corporation organized and existing under the laws of Italy, having a principal place of business at Via Palermo, 26 A, 43122 Parma, Italy.

5. Chiesi Farmaceutici S.p.A. is the current owner and assignee of each of the eight (8) patents listed in FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “Orange Book”) as covering Chiesi’s Kengreal[®], including the patent in suit. The patent in suit was previously owned by The Medicines Company, on assignment from the inventors, who were employees of The Medicines Company. Upon information and belief, The Medicines Company is a corporation having its principal place of business in Parsippany, New Jersey. Upon information and belief, one or more of the inventors of the patent in suit are located in Parsippany, New Jersey.

6. Upon information and belief, Gland is a corporation organized and existing under the laws of India, having a principal place of business at 6-3-865/1/2, Flat No. 201, Greenland Apartments, Ameerpet, Hyderabad - 500016, India.

7. Upon information and belief, Gland is in the business of, among other things, the development, manufacturing, importation, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in New Jersey. Gland's website states that Gland is "a global player with presence in about 90 countries in five continents," with "world-class manufacturing facilities accepted by global regulatory agencies including USFDA (USA)."¹ Gland's website further indicates that, in the U.S., it has 53 Abbreviated New Drug Applications (ANDAs) approved, 100 under review, and 71 under development.²

8. Upon information and belief, Gland derives substantial revenue from the sale of generic pharmaceutical products throughout the United States, including in New Jersey.

9. Upon information and belief, Gland is the current owner of ANDA No. 213551 ("Gland's ANDA") and is seeking final approval of that ANDA to engage in the commercial use, sale, and/or distribution of generic cangrelor (the "ANDA Product") throughout the United States, including in New Jersey, before the expiration of the '687 patent. Upon information and belief, Gland's ANDA included a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A) ("paragraph IV certification") to the '687 patent.

10. Upon information and belief, if Gland's ANDA receives final approval, Gland's ANDA Product will be manufactured, sold, distributed, and/or used by Gland in New Jersey;

¹ About Us, <http://www.glandpharma.com/about.html> (last visited Sept. 30, 2019).

² Business Development, <http://www.glandpharma.com/licensing.html> (last visited Sept. 30, 2019).

prescribed by physicians practicing in New Jersey; and/or administered to patients in New Jersey.

JURISDICTION AND VENUE

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

12. This Court has personal jurisdiction over Gland at least because, upon information and belief: (i) Gland manufactures generic pharmaceutical products that are imported, distributed, and sold throughout the United States—including in New Jersey—and, thus, avails itself of the privileges and benefits of the laws and commerce of the United States, including New Jersey;³ (ii) Gland regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, thereby demonstrating that Gland has continuous and systematic contacts with New Jersey; (iii) Gland's ANDA included a paragraph IV certification to the '687 patent and Gland sent notice of the paragraph IV certification to, among other locations, an address in New Jersey; (iv) Gland has previously submitted to the jurisdiction of this Court and has availed itself of New Jersey's legal protections in at least four prior

³ See Gland Pharma Ltd.'s Answer ¶ 13, *Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed May 15, 2013), ECF No. 241 (admitting that Gland "manufactures products that are sold throughout the United States, including in New Jersey"); Gland Pharma Ltd.'s Answer ¶ 4, *Medicure Int'l., Inc. v. Gland Pharma Ltd.*, No. 18-16246 (D.N.J. filed November 16, 2018), EFC No. 13 (admitting that Gland "develops, manufactures and/or distributes generic pharmaceutical products, and that certain generic pharmaceutical products developed, manufactured and/or distributed by Gland are ultimately sold in the United States, including in New Jersey.").

litigations;⁴ and (v) Gland has previously invoked this Court's jurisdiction by asserting counterclaims in at least three prior litigations.⁵

13. Under 35 U.S.C. § 271(e)(2)(A), the submission of ANDA No. 213551 with paragraph IV certification to the '687 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '687 patent is itself an act of infringement.

14. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and (c) at least because, as set forth above, Gland is subject to personal jurisdiction in this Court and has committed and will commit acts of infringement.

15. Federal venue rules do not restrict the locations in which alien corporations, like Gland, may be sued. *In re HTC Corp.*, 889 F.3d 1349, 1354–61 (Fed. Cir. 2018) (citing *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017); *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706 (1972); *In re Hohorst*, 150 U.S. 653 (1893)). For that reason, venue is proper in this Court.

FACTS AS TO ALL COUNTS

16. Chiesi's Kengreal[®] is sold and marketed under NDA No. 204958, which was approved by FDA as a New Chemical Entity (NCE) on June 22, 2015.

17. Kengreal[®] is supplied as single-use 10 mL vial containing 50 mg Kengreal[®] as a lyophilized powder for reconstitution. Cangrelor, the active ingredient in Kengreal[®], is a P2Y₁₂

⁴ See *Novartis Pharma Corp. v. Gland Pharma Ltd.*, No. 14-1841 (D.N.J. filed Mar. 21, 2014); *Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed Feb. 20, 2013); *Novartis Pharma Corp. v. Wockhardt USA LLC*, No. 12-3967 (D.N.J. filed June 27, 2012); *Medicure Int'l, Inc. v. Gland Pharma Ltd.*, No. 18-16246 (D.N.J. filed November 16, 2018).

⁵ See *Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed Feb. 20, 2013); *Novartis Pharma Corp. v. Wockhardt USA LLC*, No. 12-3967 (D.N.J. filed June 27, 2012); *Medicure Int'l, Inc. v. Gland Pharma Ltd.*, No. 18-16246 (D.N.J. filed November 16, 2018).

platelet inhibitor indicated as an adjunct to percutaneous myocardial infarction (PCI) for reducing the risk of periprocedural myocardial infarction (MI), repeat coronary revascularization, and stent thrombosis (ST) in patients in who have not been treated with a P2Y₁₂ platelet inhibitor and are not being given a glycoprotein IIb/IIIa inhibitor.

18. NDA No. 204958 pertains to Kengreal[®]'s 50 mg/vial presentation.

19. Kengreal[®]'s recommended dosage is 30 mcg/kg administered through intravenous (IV) bolus prior to percutaneous coronary intervention (PCI) followed immediately by a 4 mcg/kg/min intravenous (IV) infusion for at least 2 hours or the duration of the procedure, whichever is longer. Kengreal[®]'s prescribing information also recommends that in order to maintain platelet inhibition after discontinuation of Kengreal[®] infusion, an oral P2Y₁₂ platelet inhibitor should be administered.

20. FDA's publication, the Orange Book, lists eight (8) patents as covering Chiesi's Kengreal[®]: (1) U.S. Patent No. 10,039,780 ("the '780 patent"); (2) U.S. Patent No. 6,130,208 ("the '208 patent"); (3) U.S. Patent No. 8,680,502 ("the '502 patent"); (4) U.S. Patent No. 9,295,687 ("the '687 patent"); (5) U.S. Patent No. 9,427,448 ("the '448 patent"); (6) U.S. Patent No. 9,439,921 ("the '921 patent"); (7) U.S. Patent No. 9,700,575 ("the '575 patent"); and (8) U.S. Patent No. 9,925,265 ("the '265 patent"), (collectively, "Orange Book patents").

21. Gland sent a letter addressed to Chiesi USA Inc. and Chiesi Farmaceutici S.p.A. dated August 19, 2019, purportedly pursuant to § 505(j)(2)(B)(iv) of the FD&C Act, 21 U.S.C. § 355(j)(2)(B)(iv), and § 314.95 of Title 21 of the Code of Federal Regulations, regarding Gland's ANDA (the "Notice Letter").

22. The Notice Letter states that Gland's ANDA has been submitted under § 505(j) of the FDCA, with a paragraph IV certification to obtain approval to engage in the commercial

manufacture, use, or sale of a lyophilized formulation containing 50 mg/vial of cangrelor for injection, before the expiration of the '687 patent. The '687 patent is one (1) of the eight (8) patents listed in FDA's Orange Book as covering Kengreal®.

23. Upon information and belief, Gland's ANDA was submitted under § 505(j)(2) of the FDCA with certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '687 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the ANDA Product.

24. Upon information and belief, the prescribing information for the ANDA Product will have the same Indications and Usage as Kengreal®.

25. Upon information and belief, the prescribing information for the ANDA Product will recommend the same Dosage and Administration as Kengreal®.

26. Upon information and belief, administration of the ANDA Product, will be used to inhibit platelet aggregation in a patient in need thereof.

27. The '687 patent, titled "Pharmaceutical Formulations Comprising High Purity Cangrelor and Methods for Preparing and Using the Same," was duly and legally issued by the U.S. Patent and Trademark Office on March 29, 2016, to The Medicines Company on assignment from inventors Panna Dutta, Adel Rafai Far, Min Ding, and Rajeshwar Motheram. Subsequently, The Medicines Company assigned the '687 patent to Chiesi Farmaceutici S.p.A.

28. Pursuant to 21 U.S.C. § 355(b)(1), the '687 patent was submitted to FDA with NDA No. 204958. The '687 patent was subsequently listed in the Orange Book as covering Kengreal®.

29. But for the expiration of any patent for which certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) has been made, any final approval of Gland's ANDA shall be effective no earlier than December 22, 2022. *See* 21 U.S.C. § 355(c)(3)(E)(ii).

30. The Notice Letter does not state that Gland's ANDA contains paragraph IV certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the seven (7) other patents listed in FDA's Orange Book as covering Kengreal®: the '780 patent, the '208 patent, the '502 patent, the '448 patent, the '921 patent, the '575 patent, or the '265 patent.

31. Gland did not send a letter to Chiesi stating that Gland's ANDA contains a paragraph IV certification(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the seven (7) other patents listed in FDA's Orange Book as covering Kengreal®: the '780 patent, the '208 patent, the '502 patent, the '448 patent, the '921 patent, the '575 patent, or the '265 patent.

32. Upon information and belief, Gland's ANDA does not contain a paragraph IV certification(s) pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) for the '780 patent, the '208 patent, the '502 patent, the '448 patent, the '921 patent, the '575 patent, or the '265 patent.

33. Upon information and belief, Gland is not seeking final FDA approval of Gland's ANDA before the patent expiration for the '780 patent, the '208 patent, the '502 patent, the '448 patent, the '921 patent, the '575 patent, or the '265 patent. As indicated in FDA's Orange Book, the patent expiration for the '780 patent is July 10, 2035; the patent expiration for the '208 patent is June 29, 2023; the patent expiration for the '502 patent is May 09, 2033; the patent expiration for the '448 patent is November 10, 2030; the patent expiration for the '921 patent is July 10, 2035; the patent expiration for the '575 patent is July 10, 2035; and the patent expiration for the '265 patent is May 13, 2029.

FIRST COUNT
(Gland's Infringement of the '687 Patent)

34. Chiesi repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

35. Upon information and belief, Gland prepared Gland's ANDA.

36. Upon information and belief, Gland submitted Gland's ANDA to the FDA pursuant to § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the patent in suit. Upon information and belief, Gland's ANDA is based upon Kengreal® injection, 50 mg/10 mL, as its reference listed drug.

37. Upon information and belief, the ANDA Product is cangrelor for injection, 50 mg/10 mL vial.

38. Upon information and belief, Gland submitted Gland's ANDA with a paragraph IV certification to the '687 patent for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product before the expiration of the '687 patent.

39. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or

each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation.” 21 C.F.R. § 314.95(c)(7)(i)–(ii).

40. Upon information and belief, as of the date of Notice Letter, Gland was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

41. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Gland sent a copy of the required notice (“Gland’s Notice Letter”) to Chiesi USA Inc. at 1255 Crescent Green Drive, Suite 250, Cary, North Carolina 27518; another copy of Gland’s Notice Letter to Chiesi Farmaceutici S.p.A., Via Palermo, 26 A, 43122 Parma, Italy; another copy of Gland’s Notice Letter to Wenderoth, Lind & Ponack, LLP at 1025 Connecticut Avenue, N.W., Suite 500, Washington, DC 20036; another copy of Gland’s Notice Letter to The Medicines Company at 8 Sylvan Way, Parsippany, New Jersey 07054; and another copy of Gland’s Notice Letter to Vorys, Satar, Seymour and Pease LLP at 500 Grant Street, Suite 4900, Pittsburgh, Pennsylvania 15219-2502.

42. Under 35 U.S.C. § 271(e)(2)(A), Gland’s submission of Gland’s ANDA with a paragraph IV certification to the ’687 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland’s ANDA Product before the expiration of the ’687 patent is itself an act of infringement of the ’687 patent.

43. Upon information and belief, Gland will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States Gland’s ANDA Product upon receiving final FDA approval.

44. Upon information and belief, Gland’s commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Gland’s

ANDA Product would infringe, directly and/or indirectly, one or more of the '687 patent's claims under 35 U.S.C. § 271.

45. Upon information and belief, Gland's commercial offering for sale and/or sale of Gland's ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '687 patent under 35 U.S.C. § 271.

46. This case is "exceptional," and Plaintiffs are entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

47. The acts of infringement set forth above will cause Chiesi irreparable harm for which there is no adequate remedy at law, unless Gland is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

- (A) A judgment declaring that the '687 patent is valid and enforceable;
- (B) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Gland infringed the '687 patent by submitting to FDA Gland's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, and/or sale of Gland's ANDA Product before the expiration of the '687 patent;
- (C) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product before the expiration of the '687 patent (including any regulatory extension), would directly and/or indirectly infringe the '687 patent;

(D) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland's ANDA shall be no earlier than the date on which the '687 patent expires (including any regulatory extension);

(E) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product until the expiration of the '687 patent (including any regulatory extension);

(F) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland's ANDA shall be no earlier than the latest patent expiration for any of the patents listed in FDA's Orange Book as covering Kengreal[®], including any regulatory or patent extensions, in light of the patents that Gland is not challenging;

(G) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product until July 10, 2035 (unless there is any regulatory extension), in light of the unchallenged patents;

(H) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Chiesi damages or other monetary relief if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the

subject of Gland's ANDA, prior to the expiration of the '687 patent (including any regulatory extension);

(I) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Gland's infringement of the '687 patent is willful and awarding Chiesi enhanced damages if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '687 patent (including any regulatory extension);

(J) A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Chiesi its attorneys' fees and costs;

(K) Such other and further relief as this Court may deem just and proper.

Dated: September 30, 2019

Respectfully submitted,

By: /s/ Charles H. Chevalier

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